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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/608,987  | 06/26/2003  | John R. Hawkins      | DEP5118             | 6430             |
| 27777   | 7590        | 09/22/2004           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | RAMANA, ANURADHA    |                  |
|   |             | ART UNIT             | PAPER NUMBER        |                  |
|   |             | 3732                 |                     |                  |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                  |
|------------------------------|-----------------|------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)     |
|                              | 10/608,987      | HAWKINS, JOHN R. |
| Examiner                     | Art Unit        |                  |
| Anu Ramana                   | 3732            |                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 26 June 2003.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-29 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-29 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 26 June 2003 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/26/2003.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## **DETAILED ACTION**

### ***Claim Objections***

Claims 10 and 23 are objected to because of the following informalities. In claim 10, line 2, "(High COF)" must be deleted to correct what appears to be a typographical error. In claim 23, "silicon" should be "silicone" to correct a minor typographical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the core simulates the behavior of a natural nucleus pulposus, it cannot be harder than the sidewall of the outer shell.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5-6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, it is unclear what is being claimed. Does the upper wall have a lower thickness than the sidewall? Or, does the sidewall have a larger thickness than the upper wall?

In claim 25, line 2, the phrase "between more than 80 Shore A and 100 Shore A" renders the claim vague and indefinite since it is unclear what range the Applicant is actually claiming.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al. (US 5,545,229).

Parsons et al. disclose an intervertebral spacer or “prosthetic disc” having: (1) a central core 2; (2) a non-resorbable outer shell (8, 4 and 10) surrounding the central core wherein the outer shell approximates the size and shape of a natural annulus fibrosus; and (3) none or multiple intermediate layers provided between the core and the outer ring (Fig. 3, col. 4, lines 7-39).

Claims 1, 2, 5-6 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Zdeblick et al. (US 2002/0082701).

Zdeblick et al. disclose an artificial disc implant 110 with an elastic spacer or “central core” 116 made of an elastomer or hydrogel and a non-resorbable outer shell made of a biocompatible material such as titanium or polymers (Figs. 27-32, paras [0072]-[0073]). The outer shell inherently has hardness greater than the hardness of the core due to the material of its construction, i.e., rigid metal or polymer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 10-17 and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (US 5,545,229).

Regarding claims 3-4 and 14-15, Parsons et al. disclose that their intervertebral spacer is shaped and sized to match the properties of a normal disc. Parsons et al. disclose the claimed invention except for the upper surface and the lower surface of the outer shell to be convex, concave or flat. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Parsons et al. intervertebral spacer with different shapes and sizes, since applicant has not disclosed that these shapes solve any particular problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of shaping a intervertebral prosthesis to match the properties of a normal disc. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding claims 10, 12, 13 and 17, Parsons et al. disclose that the outer shell elements 8 can have mechanisms such as frictional fit or mechanical interlock to hold the spacer between vertebrae (col. 5, lines 11-17).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the outer surfaces of the outer shell elements 8 and 10 with a coefficient of friction of 0.5 or a roughness of no more than 0.15 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 21, 25, 26 and 27, Parsons et al. disclose that hardness of the core and outer shell is chosen such that the prosthesis reproduces the mechanical properties of the natural disc that its designed to replace. Parsons et al. also disclose that the upper and lower walls or elements 8 and 10 of the outer shell have a hardness of about 90-100 Shore A (col. 5, lines 5-9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the sidewall of the outer shell with a hardness of more than 80 Shore A, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 16 and 23, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the disc of silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein implantation in a human body, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (US 5,545,229), as applied to claim 1, in view of Higham et al. (US 2004/0054413).

Parsons et al. disclose all elements of the claimed invention except for a radiopaque marker in the outer shell or core.

Higham et al. teach providing a radiopaque implant to enable viewing of placement of the implant wherein the radiopaque material may be incorporated into the polymeric material making up the implant (Para [0026]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a radiopaque material, as taught by Higham et al., into the outer shell or core of the Parsons et al. spacer to enable viewing of placement of the spacer.

Claims 3-4, 10 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 2002/0082701).

Regarding claims 3-4 and 14-15, Zdeblick et al. disclose multiple shapes of their prosthesis to address a variety of angulations between adjacent vertebrae. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Zdeblick prosthesis with different shapes and sizes, since applicant has not disclosed that these shapes solve any particular problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of shaping a intervertebral prosthesis to match the properties of a normal disc. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding claims 10, 12, 13 and 17, Zdeblick et al. disclose that the outer shell of their prosthesis can have mechanisms such as barbs, interruptions, scales etc. to hold the prosthesis between vertebrae (Para [0081]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the outer surfaces of the outer shell elements 8 and 10 with a coefficient of friction of 0.5 or a roughness of no more than 0.15 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 18 and 19, Zdeblick et al. disclose recesses 166 and 168 in the upper and lower surface of the outer shell to receive a fastener such as a screw or "pin" (Fig. 25 and para [0091] and [0092]).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 2002/0082701), as applied to claim 1, in view of Higham et al. (US 2004/0054413).

Zdeblick et al. disclose all elements of the claimed invention except for a radiopaque marker in the outer shell or in the core.

Higham et al. teach providing a radiopaque implant to enable viewing of placement of the implant wherein the radiopaque material may be incorporated into the polymeric material making up the implant (Para [0026]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a radiopaque material, as taught by Higham et al., into the outer shell or core of the Zdeblick et al. prosthesis to enable viewing of placement of the prosthesis.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Lamara*  
September 20, 2004



EDUARDO C. ROBERT  
PRIMARY EXAMINER